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**VIA E-FILING**

The Honorable Colm F. Connolly
District Court of Delaware
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

**Re: *Alnylam Pharm., Inc. v. Moderna, Inc., et al.*, C.A. No. 22-335-CFC (Cons.)**

Dear Chief Judge Connolly:

Pursuant to the Court's April 4, 2023 Oral Order, Plaintiff Alnylam Pharmaceuticals, Inc. submits its opposition to Moderna's request for leave to amend its invalidity contentions. This case—and a related case against Pfizer—have been pending for over a year. At the Initial Scheduling Conference on September 1, 2022, the Court adopted the parties' agreed-upon date for invalidity contentions – December 13, 2022. Moderna asked for, and Alnylam agreed to, a short extension – to December 16, 2022. Moderna served its invalidity contentions on that day. In case 22-336, Pfizer similarly served invalidity contentions at approximately the same time. The two sets of contentions are markedly different. Moderna's contentions are over 450 pages, including over 400 pages of prior-art based invalidity claim charts. Pfizer's contentions contain over 1850 pages, including over 800 pages of prior-art based invalidity claim charts. Apparently unhappy with its contentions, Moderna now seeks to amend them to "incorporate by reference," i.e., cut and paste the entirety of, Pfizer's 1850 pages of contentions. By definition, everything in the Pfizer invalidity contentions was publicly available and findable before the deadline for invalidity contentions. To the extent Moderna asserts that Pfizer found publicly available prior art that Moderna did not find, that is certainly the result of a lack of diligence. To the extent Moderna argues that Pfizer's arguments are "new," that is certainly the result of Moderna's failure to think of them, not its inability to discover them. Moreover, even after Moderna obtained a copy of Pfizer's contentions in January 2023, it waited until March 30, 2023 to seek leave. It thus has not demonstrated diligence for the amendment.

Second, even if the Court believes that Moderna has acted diligently, it should deny the motion because allowing the amendment would result in prejudice to Alnylam, whose burden to defend against Moderna's invalidity contentions would significantly increase.

**Moderna has not made a "timely showing of good cause."** This Court's Scheduling Order requires a "timely showing of good cause" for amendments to contentions. D.I. 31 at ¶7. Important to this good cause analysis is whether Moderna acted with the requisite diligence in discovering the information subject to the amendment, *i.e.*, "whether they could have discovered it earlier had it acted with the requisite diligence." *Brit. Telecomm., PLC v. IAC/InterActiveCorp*, 2020 WL 3047989, at *3 (D. Del. Jun. 8, 2020); *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc*., 467 F.3d 1355, 1366 (Fed. Cir. 2006). "Unlike the liberal policy for amending pleadings, the philosophy behind amending infringement and invalidity contentions is decidedly conservative, as it is designed to 'require parties to crystallize their theories of the case early in the litigation.'" *Brit. Telecomms.*, 2020 WL 3047989, at *2 (quoting *O2 Micro*). This case has been pending since March 16, 2022. Moderna certainly could have discovered the prior art and developed the legal arguments Pfizer made by the December 2022 deadline.[1] The evidence is that Pfizer found and made them. Moderna seeks to overcome its own shortcomings by claiming Pfizer's contentions were somehow "unavailable to Moderna" and "new developments in a parallel proceeding." But any unavailability was of Moderna's own making. At the Initial Scheduling Conference, Alnylam encouraged that the 335 and 336 cases be coordinated. But Moderna and Pfizer did not agree. Indeed, the Court pressed counsel for Moderna, and Moderna expressly chose to forgo sharing knowledge with Pfizer in developing invalidity positions. D.I. 55-4 (Ex. 10) at 25:15-18 ("THE COURT: Is that a yes to my question? You are willing to forgo common interest communications? [MODERNA's COUNSEL]: Yes, to your question."). Moderna may now regret that decision, but it should not be permitted to effectively regain the benefit of Pfizer's work by arguing Pfizer's prior art and arguments were previously unavailable to Moderna.

Moreover, even after Pfizer's invalidity contentions became available to Moderna in January 2023, it waited months to seek leave. Its change in law firms and its sudden desire to shift its strategy to copy another party's arguments does not constitute good cause. *See*

[1] Moderna cites cases where an amendment was motivated by developments in co-pending IPRs, but that is not the case here. Moderna's argument that routine submission of invalidity contentions and accompanying art to the PTO during the prosecution of related family members somehow serves as an admission to prop up its good cause argument. It does not.

*Brit. Telecomms.*, 2020 WL 3047989, at *3 ("Courts have also uniformly held that a change in legal strategy does not constitute good cause to amend infringement or invalidity contentions.") (listing cases); *GlaxoSmithKline LLC v. Glenmark Pharms. Inc.*, 2016 WL 7319670, at *3 (D. Del. Dec. 15, 2016) ("new counsel's entry into a case does not serve as a magic wand that enables the party to conjure up a showing of good cause").

**Other considerations counsel against allowing the amendment.** "If the moving party can establish diligence, other considerations pertinent to the good cause inquiry come into play, including the importance of the new information, the difficulty of locating the new information, any gamesmanship that is evident from the untimely disclosure, and the potential prejudice to the opposing party that would result from permitting the belated amendment." *Brit. Telecomms.*, 2020 WL 3047989, at *2. As demonstrated above, Moderna has not established diligence. Moreover, the other pertinent factors weigh against permitting the cut-and-paste amendment. Importantly, there will be prejudice to Alnylam. Alnylam sought to have this case and the Pfizer case coordinated for discovery, but Moderna refused. D.I. 26. This lack of coordination significantly increases the burden on Alnylam. For example, Moderna and Pfizer have insisted that each is entitled to take its own depositions of Alnylam witnesses – meaning, for example, that Alnylam's inventors and expert witnesses will be subject to two separate depositions. If the amendment is permitted, there will be even more overlap in the subject matter. And, presumably, Moderna will have its own expert(s), who will surely present even similar invalidity positions differently from Pfizer's expert(s). Also, Moderna is not waiving its earlier contentions in favor of Pfizer's. Rather, it is greatly expanding the scope of this case by adding over 1850 pages and dozens of prior art references, most of which are not in Moderna's contentions. Moderna argues that Alnylam will already have to litigate the invalidity arguments in Pfizer's contentions, but Moderna seeks responsive validity contentions that Pfizer has not sought. It is of no import that Pfizer has raised the same arguments in its case. If the 336 case settles or otherwise does not go to trial, those issues would not remain because Moderna waived them absent the relief requested here.

Finally, Moderna's reliance on judicial economy is misplaced. Judicial economy is not a factor for assessing good cause. *Brit. Telecomms.*, 2020 WL 3047989, at *3; *O2*, 467 F.3d at 1366. Nonetheless, there is no judicial economy obtained by allowing the amendment as there cannot be potential inconsistent findings from different invalidity arguments.

For the foregoing reasons, the Court should deny Moderna's request.

Respectfully,

/s/ *Ethan H. Townsend*

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EHT/dar
cc: All Counsel of Record (via e-filing)